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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,941	07/10/2001	Robert A. Henderson	210121.478C17	1153

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,941	HENDERSON ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/25/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

This Office Action is responsive to the Amendment received on April 25, 2005.

Preliminary Remark

The Office acknowledges the cancellation of claim 22, in the Amendment received on April 25, 2005.

Priority

Applicants' amendment to the specification reflects the effective filing date granted (based on written description support) for the instant application, said effective filing date being April 27, 2000.

Information Disclosure Statement

The IDS received on April 25, 2005 is acknowledged.

A signed copy of the PTO-1449 is attached hereto.

Claim Rejections - 35 USC § 112

The rejection of claim 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on January 25, 2005 is withdrawn in view of the Amendment received on April 25, 2005, canceling the claim.

Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection.

In responses to an art rejection, claim 24 has been amended to become drawn to an isolated polypeptide comprising an immunogenic portion of the amino acid sequence of SEQ ID NO: 809, wherein said immunogenic portion comprises *at least ten consecutive amino acid residues of the sequence of SEQ ID NO: 809*. Hence, the claims have been narrowed from, previously claimed isolated polypeptide comprising any immunogenic portion of SEQ ID NO: 809, to a subgenus of an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 809, wherein the immunogenic portion is at least ten consecutive amino acid residues of SEQ ID NO: 809.

The application does not have written description for a broader scope of an immunogenic portion that is at least 10 consecutive amino acid sequences of SEQ ID NO: 809.

In addition, the immunogenic portion identified in claim 25 are greater than ten amino acids, specifically 19 consecutive residues of SEQ ID NO: 809. Hence, the application does not have description for the newly amended claim limitation of subgenus embracing any polypeptide comprising an immunogenic portion having the lower limit of "at least 10 consecutive amino acid residues" of SEQ ID NO: 809.

While Applicants rely on the description found on page 77, lines 5-9 of the instant specification, the description provided therein provides support for only a "fragment of the

polypeptide," but ***not*** an immunogenic portion. A fragment is clearly different from an immunogenic portion (or fragment).

Rejection – maintained

The rejection of claims 21 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description made in the Office Action mailed on January 25, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on April 25, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the same order they were presented.

Applicants contend that the amendment to claim 21 has been amended to specifically recite the identifying feature that the claimed L552S polypeptides are overexpressed in lung cancer tissue (page 5, 2nd paragraph, Response). Applicants contend that the instant specification provides more than adequate written description to support the genus of polypeptide that have at least 90% identity to SEQ ID NO: 809 and are overexpressed in lung tumor tissue. As support, Applicants refer to the examination guidelines for written description requirement set forth by the PTO, stating that a claimed genus "may be satisfied by the description of a representative number of species or the disclosure of relevant identifying characteristics." (page 5, 3rd paragraph, Response).

This argument is not found persuasive.

As already stated, a genus claim is deemed described by either: a) description of a representative number of species; or b) the disclosure of relevant identifying characteristics.

With regard to the criteria a), the instant application does not disclose a representative number of species embraced by the genus because the instant specification discloses a ***single*** species within the genus, that is, polypeptide consisting of SEQ ID NO: 809 (160 amino acid residues in length).

Hence, Applicants must rely on the criteria b) for establishing the possession of a genus, that is, an isolated polypeptide having at least 90% identity to SEQ ID NO: 809, wherein said polypeptide is overexpressed in lung cancer tissue.

The phrase, "wherein said polypeptide is overexpressed in lung cancer tissue" is not relevant identifying characteristic as provided in the Written description guidelines set forth in the examination guidelines which PTO provides.

According to Example 14 of the written description guideline, wherein a claim drawn to a protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 ***and catalyzes the reaction of A → B*** is deemed to be described when the specification conveys to a skilled artisan that a ***functional description of the protein essential to the operation*** of the claimed invention is recited in the claim. Since the procedure for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described ***which will identify other proteins having the claimed activity***, one skilled in the art would recognize that proteins which comprise the same identity ***but does not have the recited*** function ***would not be embraced by such claim***.

The instant situation is, however, is not analogous to the above situation because the instant specification evidences that Applicants have not yet identified what the function of the encoded polypeptide is:

"Initial database searches failed to detect any sequence homology with proteins in the database, suggesting that L552S (or polynucleotide of SEQ ID NO: 808) encodes a novel protein (the polypeptide of SEQ ID NO: 809) ***of unknown function***." (page 165, lines 13-15, specification).

The recitation of the phrase, "wherein said polypeptide is overexpressed in lung cancer tissue," does not cure the deficiency because the claims continue to embrace polypeptide of ***any*** function which is overexpressed and has 90% homology to SEQ ID NO: 809. One skilled in the art would not be able to recognize that Applicants were in possession of polypeptides of diverging functions which are overexpressed in lung cancer tissue.

With regard to claim 23, the application does not disclose a single species of polypeptide having 90% homology to SEQ ID NO: 809, which binds to an antibody specific for SEQ ID NO: 809, other than the actual polypeptide of SEQ ID NO: 809 itself.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Also, in University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405, the court held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude

that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

It is also noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that:

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Claim Rejections - 35 USC § 102

The rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Bevan et al. (Accession No. CAB83295, publicly available as of March 2000) in light of Hoffman et al. (U.S. Patent No. 5,095,093, issued March 10, 1992), made in the Office Action mailed on January 25, 2005 is withdrawn in view of the Amendment received on April 25, 2005, amending the claims to a polypeptide comprising an immunogenic portion, said immunogenic portion comprising at least 10 consecutive amino acid residues of SEQ ID NO: 809.

Necessitated by Amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. (U.S. Patent No. 6,639,063 B1, issued October 28, 2003, priority August 5, 1999) in light of Hoffman et al. (U.S. Patent No. 5,095,093, issued March 10, 1992[1]).

Claim 24 is drawn to any polypeptide comprising an immunogenic portion of amino acid sequence of SEQ ID NO: 809, said immunogenic portion comprising at least ten consecutive amino acid residues of SEQ ID NO: 809.

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[1] Cited in the previous Office Action mailed on January 25, 2005.

Edwards et al. disclose a polypeptide of SEQ ID NO: 5605, said polypeptide having 96 contiguous amino acid residues in common with SEQ ID NO: 809 (see homology search attached hereto).

Hoffman et al. state that a specific antibody can be generated from as little as four amino acid residues, AGDR (Abstract, column 3, lines 26-27).

Therefore, it is determined that the polypeptide of Edwards et al. would necessarily contain an immunogenic portion, as the polypeptide of Edwards et al. comprises greater than 10 consecutive amino acids in common with SEQ ID NO: 809.

According to *In re Best* 195 USPQ 430, 1997, the court stated that, "Patent Office can require applicant to prove that prior art products do not necessarily or inherently posses characteristics of his claimed product wherein claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicant" (pp. 430). Absent evidence to the contrary, the polypeptide of Edwards et al. anticipates the invention as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a

general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
7/7/2005

YOUNG J. KIM
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